IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF TEXAS, *et al.*, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 2:21-CV-00229

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

COVID-19 has "overtaken the 1918 influenza pandemic as the deadliest disease in American history." Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021), AR00001, AR00002. By the time the rule at issue here was published more than three weeks ago, SARS-CoV-2, the virus that causes COVID-19, had infected over 44 million people, hospitalized more than 3 million people, and claimed more than 720,000 lives in the United States. Those numbers continue to grow. *See* Centers for Disease Control ("CDC"), COVID Data Tracker Weekly Review, https://perma.cc/CU4F-GD9Q (updated Nov. 19, 2021). The highly transmissible virus can easily pass from person to person at health care facilities. As a result, the pandemic has been devastating for health care facilities and for patients alike. Fortunately, vaccines now approved or authorized for emergency use to protect against COVID-19 are safe and highly effective.

The Secretary of Health and Human Services reviewed this evidence and concluded that action was urgently needed to protect patients from infection with the virus while they receive care in facilities funded by Medicare and Medicaid. Congress has assigned the Secretary a statutory responsibility to ensure that the health and safety of patients are protected in these federally-funded facilities. To do so, he issued a rule requiring certain health care facilities, as a condition of their participation in these programs, to ensure that those members of their health care staffs who interact with patients, or who have contact with other staff who do so, receive vaccination for COVID-19, absent an exemption. These staff members are required to be vaccinated (or to obtain the first shot of a two-dose regimen) by December 6, or to request an exemption from this requirement from their employer. Non-exempt employees who follow a two-shot regimen must complete their second shot by January 4, 2022. The Secretary issued his rule on an emergency basis, and waived a comment period in advance of publication, because he foresaw an imminent need to protect patients against a spike in COVID-19 cases in the winter months. Although precise calculations are of course not possible, he found that his rule is likely to save hundreds, and possibly thousands, of lives each month, once it is implemented.

Plaintiffs—the State of Texas and its Health and Human Services Commission—seek to

prevent the Secretary from enforcing this rule. But this Court lacks jurisdiction over their claims. Congress has channeled jurisdiction over claims like these into an exclusive system for judicial review, under which a party must first present a particular claim for Medicare benefits, or dispute a particular sanction, to the agency for its resolution before that party may proceed to federal court. Plaintiffs have not met this prerequisite for this Court's jurisdiction.

Plaintiffs also fail to demonstrate entitlement to a preliminary injunction. In particular, they are unlikely to succeed on the merits. The Secretary has the statutory authority to ensure that federal funds are used to protect, rather than harm, the health and safety of patients receiving care in facilities that voluntarily participate in Medicare and Medicaid. He reasonably exercised that authority to arrive at his vaccination rule. He explained his determination that the rule's potential to save several hundred to several thousand lives per month compelled him to act now. In so doing, he accounted for the rule's potential costs, including that some health care workers might seek other employment rather than accept vaccination; he concluded, however, based on real-world experience with vaccination requirements, that relatively few would do so. Given that about a quarter of a health care facility's staff on average are new hires in any given year, he concluded that the effects of workers leaving for other employment to avoid vaccination, and the countervailing effects of other employees newly seeking jobs in facilities that require vaccination, would be dwarfed by the effects of this regular churn in the health care workforce. The Secretary accordingly took action, on an emergency basis, to protect lives in the coming weeks and months.

Nor can Plaintiffs meet the remaining preliminary injunction factors. The only harm Plaintiffs might have standing to assert—an alleged harm to the State's operation of its own health care facilities—is entirely speculative. The equities and public interest weigh heavily against an injunction, which would undermine the public's significant interest in protecting the health of Medicare and Medicaid patients.

For all of these reasons, Plaintiffs' motion for preliminary injunction should be denied.

BACKGROUND

I. The COVID-19 pandemic has had devastating effects on Medicare and Medicaid patients, and on health care workers.

The novel coronavirus SARS-CoV-2 causes a severe acute respiratory disease known as COVID-19. 86 Fed. Reg. at 61,556-57, AR00002-3. As of mid-October 2021, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalizations, and 720,000 COVID-19 deaths had been reported in the United States, *id.*, including over 500,000 cases and 1,900 deaths among health care staff. *Id.* at 61,559, AR00005.

Recent estimates of undiagnosed infections and under-reported deaths indicate that these figures likely underestimate the pandemic's full impact. *Id.* at 61,557 n.4, AR00003 n.4 (citing Seyed M. Moghadas and Alison P. Galvani, *The Unrecognized Death Toll of COVID-19 in the United States*, Lancet Regional Health Americas (Sept. 1, 2021), AR04073). They also fail to capture the widespread, devastating effects of post-acute illness from the virus, including long-term nervous system, neurocognitive, and cardiovascular disorders. *Id.* at 61,557 n.5, AR00003 n.5 (citing Destin Groff, et al., *Short-Term and Long-Term Rates of Postacute Sequelae of SARS-CoV-2 Infection*, JAMA Network Open (Oct. 13, 2021), AR03713).

Because the virus that causes COVID-19 is highly transmissible, it can readily spread among unvaccinated health care workers, and from these workers to patients, in health care facilities, even when infection control practices are followed. *Id.* at 61,557 n.16, AR00003 n.16 (citing, *e.g.*, Jonne J. Sikkens, et al., *Serologic Surveillance and Phylogenetic Analysis of SARS-CoV-2 Infection among Health Care Workers*, JAMA Network Open (July 28, 2021), AR03696); *id.* at 61,585 n.210, AR00031 n.210 (citing Ashley Fowlkes, et al., *Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021*, 70 Morbidity and Mortality Weekly Report 1167 (Aug. 27, 2021), AR01080). Unvaccinated health care workers are highly susceptible to transmitting the virus to their colleagues and patients. *Id.* at 61,558 n.42, AR00004 n.42 (citing, *e.g.*, Scott C. Roberts, et al., *Correlation of Healthcare Worker Vaccination with Inpatient Healthcare-Associated Coronavirus Disease 2019 (COVID-19)*,

2021 Infection Control & Hospital Epidemiology 1 (Sept. 21, 2021), AR00669). Due to many of the factors that qualify them for enrollment (*e.g.*, age, disability, and/or poverty), Medicare and Medicaid patients are more likely to face a high risk of developing severe disease and of experiencing severe outcomes from COVID-19 if infected by SARS-CoV-2. *Id.* at 61,566, 61,609, AR00012, AR00055. In short, "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action." *Id.* at 61,558, AR00004.

Unvaccinated staff also jeopardize patients' access to needed medical care and services. *Id.* Out of a fear of exposure to the virus, patients are refusing care from unvaccinated staff, thereby limiting the ability of providers to meet the health care needs of their patients. *Id.* Patients also are forgoing medically necessary care altogether to avoid contracting SARS-CoV-2 infections from health care workers. *Id.* Absenteeism from health care staff as a result of infection with the virus has also created staffing shortages that have disrupted patient access to recommended care. *Id.* at 61,559, AR00005.

In June and July 2021, an especially contagious strain of SARS-CoV-2 known as the Delta variant drove dramatic increases in COVID-19 case and hospitalization rates in the United States. *Id.* From June to September 2021, daily cases increased over 1200 percent, hospital admissions over 600 percent, and deaths over 800 percent. *Id.* at 61,583, AR00029. Cases among health care workers have "grown in tandem with broader national incidence trends since the Delta variant's emergence." *Id.* at 61,585, AR00031. The vast majority of cases during this period were among the unvaccinated population. *Id.*

In September and October 2021, reported cases began to trend downward, albeit still at highly elevated levels,[1] but at the time the Secretary issued his rule, there were troubling indications that a resurgence was coming in the next several weeks. *Id.* at 61,584, AR00030. Respiratory viruses, like SARS-CoV-2, typically circulate more frequently during the winter months, and the United States experienced a large spike in COVID-19 cases during the winter of 2020. *Id.* The 2021-2022 winter

[1] Those trends have reversed since the rule issued; since a nadir near the end of October, the moving 7 day case average has increased by nearly 50%, with a 16% increase over the last full week for which CDC reports data. See Centers for Disease Control, COVID Data Tracker Weekly Review, https://perma.cc/87MA-GNNV (updated Nov. 19, 2021).

influenza season may be an abnormally severe one, given lower immunity levels to influenza. *Id.* The interaction between the COVID-19 virus and the influenza virus may lead to particularly severe outbreaks over the next several months. *Id.* at 61,584 n.190, AR00030 n.190 (citing Sonja J. Olson, et al., *Changes in Influenza and Other Respiratory Virus Activity During the COVID-19 Pandemic – United States, 2020-2021*, 70 Morbidity and Mortality Weekly Report 1013 (July 23, 2021), AR00611). "Accordingly, it is imperative that the risk for healthcare-associated COVID-19 transmission be minimized during the influenza season." *Id.* at 61,584, AR00030.

II. Safe and effective vaccines are available to protect patients of health care facilities.

Currently, three manufacturers offer vaccines approved or authorized for emergency use in the United States by the Food and Drug Administration (FDA). *Id.* at 61,563, AR00009. FDA reviewed safety and efficacy data, and issued emergency use authorizations in December 2020 for the Pfizer-BioNTech and Moderna vaccines, and in February 2021 for the Janssen (Johnson & Johnson) vaccine. *Id.* at 61,562, 61,564, AR00008, AR00010. On August 23, 2021, based on further safety and efficacy data, FDA approved the Pfizer-BioNTech COVID-19 vaccine. *Id.* at 61,564, AR00010.

These vaccines are highly effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death. 86 Fed. Reg. at 61,565 n.115, AR00011 n.115 (citing https://perma.cc/3FC6-X47H, AR00856). The available evidence indicates that these vaccines offer strong protection against known variants of the virus, including the Delta variant, particularly against hospitalization and death. *Id.* at 61,565 n.116, AR00011 n.116 (citing Mark W. Tenforde, et al., *Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021*, 70 Morbidity and Mortality Weekly Report 1156 (Aug. 27, 2021), AR03974). The available evidence also indicates that the vaccines offer better protection than infection-induced immunity alone does. *Id.* at 61,559-60, AR00005-06. Even for persons with prior SARS-CoV-2 infections, vaccination helps prevent reinfection. *Id.* at 61,585 n.205, AR00031 n.205 (citing Alyson M. Cavanaugh, *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021*, 70 Morbidity and Mortality Weekly Report 1081 (Aug. 13, 2021), AR03415); *see also* CDC, *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced immunity*,

https://perma.cc/MTW9-3KU4 (updated Oct. 29, 2021), AR04481).

Recent studies indicate that the vaccines are 80 percent effective in preventing SARS-CoV-2 infection among frontline workers—more effective in practice than are existing protocols, such as protocols for regular testing. *Id.* at 61,566 n.118, AR00012 n.118 (citing Ashley Fowlkes, et al., *Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021*, 70 Morbidity and Mortality Weekly Report 1167 (Aug. 27, 2021), AR01080); *id.* at 61,585 n.210, AR00031 n.210 (citing, *e.g.*, Michael Klompas, et al., *Transmission of SARS-CoV-2 From Asymptomatic and Presymptomatic Individuals in Healthcare Settings Despite Medical Masks and Eye Protection*, 73 Clinical Infectious Diseases 1693 (Nov. 2, 2021), AR04095).

Like all vaccines, the COVID-19 vaccines are not 100 percent effective at preventing infection, and some breakthrough cases are expected among people with full vaccination. However, the risk of developing COVID-19 remains much higher for unvaccinated than vaccinated people, and therefore could lead to higher absenteeism rates for unvaccinated staff in healthcare settings. *Id.* at 61,559, 61,565 n.120, AR00005, AR00011 n.120. Vaccinated people with breakthrough COVID-19 cases are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID-19. *Id.* at 61,565 n.120, AR00011 n.120 (citing https://perma.cc/7BCX-8QKS, AR04060). Studies have shown that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer opportunities for transmission. *Id.* at 61,558 n.37, AR00004 n.37 (citing, *e.g.*, Marc M. Shamier, et al., *Virological Characteristics of SARS-CoV-2 Vaccine Breakthrough in Health Care Workers* (Aug. 21, 2021), https://perma.cc/KMK4-XLE9, AR04290).

III. The Social Security Act grants the Secretary the authority to protect the health and safety of patients in facilities funded by the Medicare and Medicaid programs.

Congress established the Medicare program "[a]s a means of providing health care to the aged and disabled." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993); *see* 42 U.S.C. § 1395 *et seq.* Congress also created the Medicaid program to "furnish medical assistance" (i.e., health care) on behalf

of individuals "whose income and resources are insufficient to meet the costs of necessary medical services[.]" 42 U.S.C. § 1396-1. Under both programs, health care services are provided by private health care organizations and professionals who meet the statutory and regulatory requirements for participation.

To participate in Medicare, providers such as hospitals, home-health agencies, hospices, and skilled nursing facilities voluntarily enter into a provider agreement with the Centers for Medicare & Medicaid Services (CMS) after demonstrating that they meet the conditions for participation. *Id.* § 1395cc. Medicaid providers, likewise, voluntarily enter into provider agreements with State Medicaid agencies to be eligible for participation in that program. *Id.* § 1396a(a)(27). By entering into the provider agreement, a facility agrees that it will comply with the Medicare and Medicaid statutes and with the Secretary's regulations under these statutes. *See id.* §§ 1395cc(b)(2); 1396a(p)(1).

The Secretary has authority under the Social Security Act and under the Medicare statute to issue such rules and regulations "as may be necessary to the efficient administration of the functions with which" he is charged under each statute. 42 U.S.C. § 1302(a); *see also id.* § 1395hh(a)(1). He is charged with issuing regulations as he deems necessary to, *inter alia*, ensure that the health and safety of patients are protected while these individuals receive care that is funded by either program. *See, e.g.*, *id.* § 1395x(e)(9) (a "hospital" must "meet[] such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution"); *id.* § 1395i-3(d)(4)(B) (same with respect to skilled nursing facilities). These regulations are alternatively known as "conditions of participation," "conditions for coverage," or "requirements for participation."

The Secretary's long-standing conditions of participation include detailed requirements governing, among other things, the qualifications of professional staff, the condition of facilities, and other requirements that he deems necessary to protect patient health and safety. In particular, the regulations require that facilities maintain effective "infection prevention and control programs," and "provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections." 42 C.F.R. § 483.80; *see also, e.g.*, *id.*

§§ 482.42(a); 416.51(b).

The Secretary may enter into agreements with States under which a state health agency conducts periodic surveys to assess whether providers meet Medicare's conditions of participation. 42 U.S.C. § 1395aa(a); *see also* 42 C.F.R. § 488.10(a). A State's decision to enter into a survey agreement is voluntary, *see* 42 U.S.C. § 1395aa(a), but by entering into such an agreement, a State obliges itself to conduct surveys to "assess compliance with Federal health, safety and quality standards," 42 C.F.R. § 488.26(c)(1), using "the survey methods, procedures, and forms that are prescribed by CMS," *id.* § 488.26(d). State survey agencies review facilities for compliance and present findings to CMS, *see id.* § 488.12, but CMS has sole authority to determine noncompliance and impose remedies on Medicare providers, *see* 42 U.S.C. § 1395i-3(h)(2). *See also id.* §§ 1395i-6(c), 1395bbb(e), 1395cc(b)(2).

If a provider fails to comply with conditions of participation, CMS may, upon notice, terminate the provider's participation in the Medicare program, *see* 42 U.S.C. § 1395cc(b)(2); 42 C.F.R. § 489.53, or in some circumstances, impose monetary penalties, *see, e.g.*, 42 U.S.C. § 1395bbb(e), (f); 42 C.F.R. § 488.820. A facility may appeal CMS's "initial determination," including a "finding of noncompliance leading to the imposition of enforcement actions," 42 C.F.R. § 498.3(b)(13), and is entitled to a *de novo* hearing before an administrative law judge ("ALJ"). *Id.* §§ 498.40-498.79. A facility may appeal an ALJ's determination to the Departmental Appeals Board. *Id.* § 498.80. The Board's decision is the final decision of the Secretary. *Id.* § 498.90. The Medicare statute allows a provider to seek judicial review of the "final decision" of the Secretary. *See* 42 U.S.C. § 1395cc(h)(1)(A) (cross-referencing 42 U.S.C. § 405(g)). This avenue of judicial review is exclusive. 42 U.S.C. § 405(h) (incorporated into Medicare by 42 U.S.C. § 1395ii); *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000).

IV. Recent developments have revealed an urgent need for further action to protect the health of Medicare and Medicaid patients.

As noted above, the emergence of the Delta variant over the summer months led to a dramatic spike in cases, hospitalizations, and deaths caused by COVID-19, a resurgence that has been driven by the spread of infection among the unvaccinated population. The Secretary's initial policy approach, after vaccines became available to the general population during the early months of 2021, was "to

encourage rather than mandate vaccination." 86 Fed. Reg. at 61,583, AR00029. It appeared at the time that "a combination of other Federal actions, a variety of public education campaigns, and State and employer-based efforts would be adequate." *Id.* Unfortunately, that turned out not to be the case—"vaccine uptake among health care staff has not been as robust as hoped for and ha[s] been insufficient to protect the health and safety of individuals receiving health care services" from covered providers. *Id.* Vaccination rates among health care workers averaged 67%, 64%, or 60% for long-term care facility staff, hospital staff, and end-stage renal disease facility staff, respectively. *Id.* at 61,559, AR00005. In September 2021, the President announced his COVID-19 Action Plan, which announced a series of regulatory actions that federal agencies were planning to undertake in response to the pandemic. As relevant here, the announcement described CMS's plans to require vaccinations for health care workers at Medicare- and Medicaid-participating facilities. The White House, Path Out of the Pandemic, https://perma.cc/M4GG-HB2Q (last visited Nov. 24, 2021).

V. The Secretary issued the vaccination rule to protect the health and safety of Medicare and Medicaid patients from the transmission of SARS-CoV-2 in health care facilities.

On November 5, 2021, CMS published the interim final rule at issue here, which requires various categories of Medicare and Medicaid providers and suppliers to develop and implement plans and policies to "ensure staff are fully vaccinated for COVID-19, unless exempt, because vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished." 86 Fed. Reg. at 61,561, AR00007. Vaccination and accompanying documentation are required for any non-exempt staff that "interact with other staff, patients, residents, clients, or [elderly care] program participants in any location[.]" *Id.* at 61,568, 61,570, AR00014, AR00016. Facilities must develop policies to permit their staff to request exemptions from the vaccination requirement, given that staff "who cannot be vaccinated or tested because of an ADA disability, medical condition, or sincerely held religious belief, practice, or observance may in some circumstances be granted an exemption from their employer." *Id.* at 61,572, AR00018.

Under the rule, all relevant staff must receive the first dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine, or request or have been granted an exemption under the health

care facility's exemption policies, and all facilities subject to the rule also must have developed and implemented policies and procedures to vaccinate staff by December 6, 2021. *Id.* at 61,573, AR00019. By January 4, 2022, all non-exempt staff covered by the rule must be fully vaccinated. *Id.* The rule states that CMS will issue interpretive guidelines regarding assessment of compliance with these requirements, and providers and suppliers cited for noncompliance may be subject to enforcement remedies depending "on the level of noncompliance and the remedies available under Federal law[.]" *Id.* at 61,574, AR00020.

The Secretary also concluded that there was good cause to waive the notice-and-comment process in rulemaking. He explained in detail how "current levels of COVID-19 vaccination coverage up until now have been inadequate to protect health care consumers and staff," and demonstrated a "pressing need for a consistent Federal policy mandating staff vaccination in health care settings that receive Medicare and Medicaid funds." *Id.* at 61,583-84, AR00029-30. In particular, the Secretary reasoned that there was a pressing need for action in light of the coming winter influenza season, which he noted could be particularly intense and could lead to a dramatic increase in both influenza and COVID-19 cases among vulnerable populations, including Medicare and Medicaid beneficiaries. *Id.* at 61,584, AR00030. These findings demonstrated to the Secretary that "a vaccine mandate for healthcare workers is an essential component of the nation's COVID-19 response, the delay of which would contribute to additional negative health outcomes for patients *including loss of life*." *Id.* (emphasis added). Thus, CMS concluded "it would endanger the health and safety of patients, and be contrary to the public interest to delay" issuance of a vaccine requirement for staff in healthcare settings. *Id.* at 61,586, AR00032.

VI. This litigation is brought.

Plaintiffs challenge the rule, asserting claims purportedly arising under the Administrative Procedure Act ("APA"), the Social Security Act, and Article I and the Tenth Amendment to the United States Constitution. Compl. ¶¶ 148-319, ECF No. 1. Plaintiffs filed their Complaint on November 15, 2021. *See* Compl. On November 16, 2021, Plaintiffs moved for a preliminary injunction and temporary restraining order. Pls.' Br. in Supp. of Mot. for TRO & Prelim. Inj., ECF No. 7 ("Br.").

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary and drastic remedy" that should "never be awarded as of right." *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008) (citation omitted). A plaintiff may obtain this "extraordinary remedy" only "upon a clear showing" that it is "entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The plaintiff must show (1) "a substantial threat of irreparable injury," (2) "a substantial likelihood of success on the merits," (3) "that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted," and (4) "that the grant of an injunction will not disserve the public interest." *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (quoting *Sepulvado v. Jindal*, 729 F.3d 413, 417 (5th Cir. 2013)). The plaintiff must "clearly carr[y] the burden of persuasion on all four requirements." *Id.* (citation omitted); *see also, e.g.*, *Lake Charles Diesel, Inc., v. Gen. Motors Corp.*, 328 F.3d 192, 203 (5th Cir. 2003).

ARGUMENT

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THEIR CLAIMS BECAUSE THE MEDICARE STATUTE'S CHANNELING PROVISION DEPRIVES THIS COURT OF JURISDICTION OVER SUCH CLAIMS.

Plaintiffs dispute the validity of the vaccination rule, arguing that health care facilities in Texas should not be subject to any sanction, in the form of loss of Medicare funding or eligibility for participation in the Medicare program, for a violation of the rule. This Court lacks jurisdiction over these claims. Claims arising under the Medicare statute must be channeled through that statute's exclusive channeling provisions, which bars pre-enforcement challenges.

The Medicare statute "channels most, if not all, Medicare claims through [a] special review system." *Illinois Council*, 529 U.S. at 8; *see also Sw. Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 440 (5th Cir. 2013). Under 42 U.S.C. § 1395cc(h)(1), for example, a provider dissatisfied with the agency's decision to terminate its Medicare agreement is entitled to "a hearing thereon by the Secretary" and to "judicial review of the Secretary's final decision" as is provided in 42 U.S.C. § 405(g). Congress made this avenue of judicial review exclusive. The statute provides that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein

provided." 42 U.S.C. § 405(h) (made applicable to the Medicare statute by 42 U.S.C. § 1395ii). And the same provision also forecloses any alternative bases for jurisdiction, such as federal-question jurisdiction, over any claim "arising under" the Medicare statute. *Id.*; *see also Illinois Council*, 529 U.S. at 10; *Smith v. Berryhill*, 139 S. Ct. 1765, 1772 (2019) ("Congress made clear that review would be available only 'as herein provided'—that is, only under the terms of § 405(g).").[2]

In *Illinois Council*, the Supreme Court concluded that the federal courts lacked jurisdiction over constitutional, statutory, and APA claims brought by an association of nursing home operators, which had asserted that pre-enforcement review was needed of the facial validity of a Medicare regulation governing termination procedures for nursing homes found to be in violation of their conditions of participation. The Court held that claims involving the Medicare program may not be brought in federal court before a party first presents its claim to the agency; "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies,'" which are subject to well-established exceptions, and instead "demands the 'channeling' of virtually all legal attacks through the agency." *Illinois Council*, 529 U.S. at 12–13. This stringent requirement "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying 'ripeness' and 'exhaustion' exceptions case by case." *Id.* at 13.

The Supreme Court recognized that "this assurance comes at a price, namely, occasional individual, delay-related hardship." *Id.* at 13. But, the Court explained,

> In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified.

[2] In addition to asserting federal-question jurisdiction under 28 U.S.C. § 1331, Plaintiffs also invoke the Declaratory Judgment and Mandamus Act, 28 U.S.C. §§ 2201 and 1361. The Declaratory Judgment Act is not an independent source of jurisdiction. *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 767 (5th Cir. 2011). And mandamus is only available to order "a precise, definite act about which an official ha[s] no discretion whatever," *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (cleaned up), not "to prohibit the defendants from acting in a certain manner in the future." *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 505–06 (5th Cir. 2018) (citation omitted). Plaintiffs here seek to invalidate a regulation, not to compel the performance of a ministerial duty.

Id. At least, "such was the judgment of Congress." *Id.*; *see also Heckler v. Ringer*, 466 U.S. 602, 627 (1984).

Illinois Council emphasized the broad reach of the channeling requirement. The Supreme Court explained that its decisions "foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'non-collateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought." *Illinois Council*, 529 U.S. at 13–14. The Court also explained that the channeling requirement is not limited to particular types of relief. "Claims for money, claims for other benefits, *claims of program eligibility*, and *claims that contest a sanction or remedy*," the Court noted, "may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions." *Id.* at 14 (emphasis added). The Court found "no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h)." *Id.*; *see also Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 656 (5th Cir. 2012).

Plaintiffs' claims are subject to the jurisdiction-channeling provision of § 405(h), and federal-question jurisdiction is barred, if they arise under the Medicare statute, even if they also arise under the Constitution or under other statutes such as the Administrative Procedure Act. A claim "arises under" the Medicare statute if "both the standing and the substantive basis for the presentation" of the claim is the statute, or if it is "inextricably intertwined with a claim for benefits." *Ringer*, 466 U.S. at 614-15; *see also Physician Hosps.,* 691 F.3d at 656. The "arising under" inquiry looks to the claim's "essence," and "not whether [the claim] lends itself to a 'substantive' rather than a 'procedural' label." *Ringer*, 466 U.S. at 614-15, 624. Accordingly, this rule applies not only to "a claim for future benefits," but also to "all aspects" of any such present or future claim, including requests for injunctive and declaratory relief. *See Illinois Council*, 529 U.S. at 12-14 (quoting *Ringer*, 466 U.S. at 614-15).

Under this standard, Plaintiffs' claims plainly "arise under" the Medicare statute. Plaintiffs, acting purportedly on behalf of several state-run health care facilities and as *parens patriae* for privately-run health care facilities in Texas, challenge the Secretary's statutory authority under the Medicare statute to issue the vaccination rule. They seek pre-enforcement review to challenge the Secretary's

authority to impose the Medicare statute's remedies of civil monetary penalties, withholding of payments, or termination on facilities that violate the rule. The standing and substantive basis for these claims arise under the Medicare statute, and they are inextricably intertwined with facilities' claims that they should continue to receive the benefit of eligibility to participate in the Medicare program, without sanction, even if they do not comply with the vaccination rule. *See Blue Valley Hosp. v. Azar*, 919 F.3d 1278, 1283 (10th Cir. 2019).[3]

The Supreme Court has recognized a narrow exception to § 405(h)'s jurisdictional bar; the Court presumes that Congress did not intend to preclude review when the application of the channeling requirement "would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 529 U.S. at 19.[4] But Plaintiffs may not invoke this exception simply by alleging that financial hardship forecloses further review. *See id.* at 22; *see also Sw. Pharmacy Sols., Inc.*, 718 F.3d at 441 ("The fact that a plaintiff would suffer great hardship if forced to proceed through administrative channels before obtaining judicial review is insufficient to warrant application of the *Illinois Council* exception."). "[T]he 'channeling' of virtually all legal attacks through the agency . . . comes at a price, namely, occasionally individual, delay-related hardship," but Congress nonetheless deemed that price "justified" when it enacted the Medicare statute. *Illinois Council*, 529 U.S. at 13. The question instead is "whether, as applied generally . . . hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete preclusion* of judicial review." *Id.* at 22-23 (emphasis added); *see also Physician Hosps. of Am.*, 691 F.3d at 659.

The application of § 405(h) here would not result in the "complete preclusion" of judicial

[3] The conditions of participation regulations are common Medicare and Medicaid regulations, which are enforced through a unitary enforcement scheme that determines eligibility and penalties under both programs. Because this system requires review of these determinations "through the Medicare administrative appeals procedure," the channeling requirement of § 405(h) applies fully to challenges to these regulations. *Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 366 (6th Cir. 2000); *see also In re Bayou Shores SNF, LLC*, 828 F.3d 1297, 1330 (11th Cir. 2016); 42 U.S.C. § 1396i(b)(2).

[4] A second narrow exception applies where a plaintiff has presented its claim to the agency, and either the agency or the court finds adequate grounds to excuse further exhaustion of that claim. But even where exhaustion might be excused, the presentment of a claim to the agency is a non-waivable jurisdictional requirement under § 405(h). *See Illinois Council*, 529 U.S. at 15; *Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 284 (5th Cir. 1999). Plaintiffs presented no claim to the agency to contest an enforcement action, and so this exception cannot apply here.

review of the Secretary's vaccination rule. A provider or supplier that violates the rule and is subject to an enforcement action could exhaust its remedies before the agency and then proceed to federal court. 42 U.S.C. § 1395cc(h). Alternatively, such a facility, upon receiving notice of a potential sanction and after filing an appeal before an ALJ, "shall have expedited access to judicial review" that will permit the facility to proceed directly to federal court to challenge the legality of the rule. *Id.* § 1395cc(h)(1)(B). Far from a "complete preclusion" of review, the Medicare statute sets forth an orderly procedure for parties to contest the legality of sanctions that the Secretary would seek to impose on them. *See Illinois Council*, 529 U.S. at 19.

It is true, of course, that State governments are not "dissatisfied" "institution[s] or agenc[ies]" within the meaning of 42 U.S.C. § 1395cc(h)(1), and thus States themselves could not use that statute's vehicle for judicial review, although individual state-operated facilities could do so once they are cited for a violation. But the same point was true of the plaintiff in *Illinois Council*, and the Supreme Court held that that was immaterial. It is the "rights to review" of health care facilities subject to the vaccination rule "that are at stake," and "the statutes that create the special review channel adequately protect those rights." *Illinois Council*, 529 U.S. at 24; *see also Sw. Pharmacy Sols.*, 718 F.3d at 444-46; *Physician Hosps. of Am.*, 691 F.3d at 659. Health care facilities that are aggrieved by the enforcement of the vaccination rule may seek review of that rule after following the jurisdictional requirements of § 405(h). State governments, however, may not skip the jurisdictional requirements to litigate on their behalf.[5]

II. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS.

A. CMS has statutory authority for the rule.

As noted above, the Secretary has broad authority under the Social Security Act to issue such regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Act. 42 U.S.C. § 1302(a); *see also id.* § 1395hh(a)(1). Binding Supreme Court and

[5] At all events, Plaintiffs' claims against President Biden must be dismissed for lack of jurisdiction, because the courts have "no jurisdiction of a bill to enjoin the President in the performance of his official duties." *Franklin v. Massachusetts*, 505 U.S. 788, 803 (1992).

Fifth Circuit case law confirms the extent of the Secretary's authority under these statutes. Addressing similar enabling language in other statutes, the Supreme Court has concluded that this language grants the agency "broad authority." *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 365 (1973) (quotation marks omitted). More specifically, "[w]here the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,'" the Court held that "the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Id.* at 369 (quoting *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 280-81 (1969)).

Applying this standard, the Supreme Court has recognized that § 1302(a) confers "broad rule-making powers . . . in substantially the same language" as the rulemaking provision in the cases cited above. *Thorpe*, 393 U.S. at 277 n.28; *see also Blum v. Bacon*, 457 U.S. 132, 140 n.8 (1982) (same). Because the rulemaking provision of the Social Security Act, § 1302(a), contains essentially the same terms as were at issue in *Mourning* and *Thorpe*, the Fifth Circuit applies the same "reasonably related" standard in reviewing an attack on the Secretary's authority to promulgate regulations under § 1302(a). *See Baylor Univ. Med. Ctr. v. Heckler*, 758 F.2d 1052, 1062 (5th Cir. 1985).

The vaccination rule is comfortably within the Secretary's statutory authority under this standard. As noted above, Congress created both the Medicare and Medicaid programs as a means to provide health care to the populations covered under each program. *See Good Samaritan Hosp.,* 508 U.S. at 404; *see also* 42 U.S.C. § 1396-1. The purpose of providing health care services to these populations, of course, is to advance and maintain patients' health, not to harm them. It is therefore unsurprising that Congress has taken care to instruct the Secretary to administer these programs in a way that ensures that the health and safety of patients are protected. Throughout the Medicare statute, Congress has directed the Secretary to use the various tools at his disposal to ensure that health care facilities do not cause harm to their patients. *See, e.g.*, 42 U.S.C. § 1395aa(a) (instructing the Secretary to impose any conditions on facilities found to be noncompliant that he "finds necessary in the interest of health and safety of individuals who are furnished care or services" at the facility); *id.* § 1396a(a)(36) (same); *see also id.* § 1395bb(c); 1395bbb(b).

Of particular relevance here, numerous provisions throughout the Medicare and Medicaid statutes charge the Secretary with the responsibility to issue regulations, as he deems necessary, that condition health care facilities' eligibility for the Medicare and Medicaid programs on those facilities' ability to protect the health and safety of their patients while those patients are receiving care that is funded by either program. *See, e.g.*, 42 U.S.C. § 1395x(e)(9) (defining a "hospital" as an institution which, among other things, "meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution"); *id.* § 1395i-3(d)(4)(B) ("A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary."); *id.* § 1395i-3(f)(1) (instructing the Secretary to ensure that regulatory requirements for skilled nursing facilities "are adequate to protect the health, safety, welfare, and rights of residents").[6]

These provisions of the Medicare and Medicaid statutes operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard [patients'] health and safety and protect their dignity and rights." *Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021) (discussing § 1395i-3(f)(1)). The statutes thus accord the Secretary the authority, and the responsibility, to impose conditions of participation on health care facilities so as to protect patients' health and safety—a responsibility that has taken on paramount importance since the onset of the COVID-19 pandemic. The Secretary, at least, reasonably understood his authority to encompass this responsibility, and that understanding is entitled to deference from this Court. *See id.*

Plaintiffs do not dispute that a rule requiring the vaccination of health care facility employees protects the "health and safety" of those facilities' patients, as those words are ordinarily understood. Instead, they contend, based on canons such as the "major question" doctrine, that the statutes' failure to expressly address vaccinations means that Congress intended to deny the Secretary the authority to

[6] A complete list of the Secretary's authorities with respect to health and safety standards for the various types of providers and suppliers covered under the rule may be found at 86 Fed. Reg. at 61,567, AR00013.

use this tool to protect the health and safety of patients. Br. 26-27. But the canons of interpretation on which Plaintiffs rely "may only be used where words are of obscure or doubtful meaning." *Iverson v. United States*, 973 F.3d 843, 853 (8th Cir. 2020) (citing *Russell Motor Car Co. v. United States*, 261 U.S. 514, 520 (1923)). Here, where the words "health" and "safety" have "a character of [their] own" that plainly encompasses the avoidance of a deadly disease, the canon has no application. *Russell Motor Car Co.*, 261 U.S. at 519. And, in any event, these canons do not apply "unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it." *Coastal Conservation Ass'n v. U.S. Dep't of Com.*, 846 F.3d 99, 106 (5th Cir. 2017) (quoting *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 381 (2013)). Plaintiffs can point to no statutory text that would indicate that Congress means the phrase "health and safety" to mean anything other than the natural implication of those words, which would include the protection of patients from contracting infectious diseases during their stays at Medicare- and Medicaid-funded facilities.

For this reason, Plaintiffs' reliance on *Alabama Association of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is misplaced. The Supreme Court in that case rejected the issuance of a national eviction moratorium by the Centers for Disease Control and Prevention under a different statute, reasoning that a "downstream connection between eviction and the interstate spread of disease is markedly different from the direct targeting of disease that characterizes the measures identified in [that] statute." *Id.* at 2488. The Secretary here is not seeking to regulate the "downstream" effects of the pandemic. Rather, the statutes directly instruct him to protect the health and safety of beneficiaries of the Medicare and Medicaid programs, while those individuals are receiving care that is paid for by either program. Because the Secretary determined that the virulence of SARS-CoV-2 poses a unique threat to patients' health and safety in these settings, and that vaccines are an effective means of reducing and preventing transmission of the virus, he discharged his statutory responsibility by issuing his vaccination rule. *See generally Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537-38 (D.C. Cir. 2020) (distinguishing, for purposes of Sections 1302 and 1395hh, between an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" and a valid rule that has "an actual and discernible nexus between the rule and the conduct

or management of Medicare and Medicaid programs").

Plaintiffs contend that the Secretary's health-and-safety authority should be read narrowly, because the vaccination rule threatens to interfere with state authority over public health, which is an area "within the States' police powers." Br. 14.[7] The Medicare and Medicaid statutes are provisions enacted under the Spending Clause, however. As noted, Congress has charged the Secretary with the responsibility to ensure that federal funds are used in the way that Congress directed, and this includes the responsibility to protect the health and safety of patients at facilities funded by these programs. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare, [and] to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies even when Congress legislates "in an area historically of state concern." *Id.* at 608 n.*. The Secretary did not intrude on state police powers when he issued his vaccination rule, then, any more than he did when he issued his long-standing rules conditioning federal funds on providers' commitment to prevent the spread of infection within those facilities. *See, e.g.*, 42 C.F.R. §§ 416.51(b), 482.42(a), 483.80.[8]

Plaintiffs also invoke the nondelegation doctrine to contend that Congress could not delegate to the Secretary the authority to protect the health and safety of patients at Medicare and Medicaid facilities. Br. 12. But "[d]elegations are constitutional so long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the authority is directed to conform." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (cleaned up), *cert. denied*, 141

[7] Plaintiffs' further assertion that the States are "commandeered" into enforcing the vaccination rule, Br. 35, is meritless. A State's decision to operate a state survey agency, and to review facilities' compliance with conditions of participation, is entirely voluntary. 42 U.S.C. § 1395cc(a). And state survey agencies do not "enforce" the conditions of participation; instead, they report their findings to CMS, which makes a determination whether to pursue a sanction. 42 C.F.R. §§ 488.10(a), 488.26(c)(1). *See also* 42 C.F.R. § 488.11 (state survey agency functions do not include enforcement).

[8] For the same reason, Plaintiffs' repeated invocations of the Fifth Circuit's decision on a stay application in *BST Holdings, L.L.C. v. OSHA*, , --- F.4th ----, 21-60845, 2021 WL 5279381 (5th Cir. Nov. 12, 2021), are entirely misplaced. That case involved a different statute, under which OSHA exercised regulatory power granted to it under the commerce power, and the court expressed concerns as to the reach of the agency's general regulatory power. This case involves Congress's exercise of its power to place conditions on the use of federal funds, and health care facilities' voluntary decision to accept those conditions when they participate in the Medicare and Medicaid programs.

S. Ct. 2746 (2021). The Secretary's statutory authority to protect the health and safety of Medicare and Medicaid patients easily meets this minimal standard. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 473 (2001) (upholding "public health" standard).

Finally, Plaintiffs contend that the rule violates 42 U.S.C. § 1395, in that the Secretary has purportedly asserted control over the selection of health care facility employees or the administration of health care institutions. This assertion misconstrues the nature of the Medicare and Medicaid programs, and of the vaccination rule. Health care facilities voluntarily participate in the Medicare and Medicaid programs. *See Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991). If they choose to do so, they must "meet certain conditions of participation established by the Secretary" in order to receive federal payments under these programs. *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1044 (5th Cir. 1984). Those conditions on federal funding have long included detailed rules addressing the qualifications of employees at health care facilities. *See, e.g.*, 42 C.F.R. § 482.22 (standards for medical staff at hospitals). The Secretary's vaccination rule, like these other rules addressing employee qualifications, ensures that federal funds are used only to pay for the purposes that Congress intended. Because the vaccination rule is not a legal mandate, but instead a condition imposed on the payment of federal funds, the rule does not assert "control" over the administration of institutions. *See Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) ("The regulation does not actually direct or prohibit any kind of treatment or diagnosis. It only refuses subsequent Medicare reimbursement for certain kinds of services."); *see also Am. Acad. of Ophthalmology, Inc. v. Sullivan*, 998 F.2d 377, 387 (6th Cir. 1993).

B. The rule is the product of reasoned decisionmaking.

Plaintiffs contend that the Secretary acted arbitrarily by issuing a rule to protect the health and safety of Medicare and Medicaid patients. This Court reviews this claim under 42 U.S.C. § 405(g), which provides that the Secretary's findings, "if supported by substantial evidence, shall be conclusive." Even assuming that this statute incorporates the Administrative Procedure Act's standard for arbitrary-and-capricious review, *but see Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000), that standard is easily met here.

The APA's arbitrary-and-capricious standard is "narrow and highly deferential." *Sierra Club v. United States Dep't of Interior*, 990 F.3d 909, 913 (5th Cir. 2021) (citation omitted). "[T]he 'court is not to substitute its judgment for that of the agency." *Id.* (citation omitted). Rather, the court "consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation omitted). In short, the arbitrary-and-capricious standard simply "requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The Secretary considered all the relevant factors, and reasonably explained his decision, when he issued his rule to protect Medicare and Medicaid patients from the transmission of a deadly virus at facilities funded by these programs. The APA requires nothing more.

Protection of the Health and Safety of Medicare and Medicaid Patients. The Secretary's primary responsibility is to protect the health and safety of patients receiving care at Medicare- and Medicaid-funded facilities. He considered the available evidence and reasonably concluded that the rule would protect these patients' health and safety; indeed, the record overwhelmingly points to this conclusion.

SARS-CoV-2 is highly transmissible, and extremely dangerous. 86 Fed. Reg. at 61,556-57, AR00002-03. By the time this rule was published, COVID-19 had caused the deaths of at least 720,000 people in the United States, including at least 1,900 health care workers, and hospitalized at least 3 million people. *Id.* at 61,556, 61,569, AR00002, AR00015. It is "the deadliest disease in American history." *Id.* at 61,556, AR00002. Given the virulence of this virus, it can be easily transmitted among health care workers, and from health care workers to patients, in health care facilities. *Id.* at 61,557 n.16, AR00003 n.16. Unvaccinated health care workers are highly susceptible to becoming infected and then transmitting the virus to colleagues and patients. *Id.* at 61,558 n.42, AR00004 n.42. Due to many of the factors that qualify participants in the Medicare and Medicaid programs for enrollment (e.g., age, disability, and/or poverty), patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19. *Id.* at 61,609, AR00055. For these reasons, "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action." *Id.* at 61,558, AR00004.

Medicare and Medicaid beneficiaries' access to needed medical care is jeopardized by low rates of vaccination among health care workers at facilities funded by these programs. *Id.* Program patients have refused care from unvaccinated staff, or forgone care altogether, to avoid contracting the virus from health care workers. *Id.* Absenteeism due to SARS-CoV-2 infection and COVID-19 illness has contributed to staffing shortages that disrupt patient access to recommended care. *Id.* at 61,559, AR00005.

Fortunately, the approved or authorized COVID-19 vaccines are safe, 86 Fed. Reg. at 61,562, AR00008 and highly effective in preventing serious outcomes of COVID-19, *id.* at 61,565 n.115, AR00011, AR 00856. They offer strong protection against known variants of the virus, including the Delta variant, particularly against hospitalization and death. *Id.* at 61,565 n.116, AR00011 n.116, AR 03974. Recent studies show that the vaccines are highly effective in preventing SARS-CoV-2 infection among frontline workers. *Id.* at 61,585 n.205, AR00031 n.205, AR 00797. Studies also show that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer transmission opportunities. *Id.* at 61,558 n.37, AR00004 n.37, AR 04290.

In short, evidence overwhelmingly points to the conclusion that SARS-CoV-2 is extremely dangerous for Medicare and Medicaid patients, and that health care staff vaccination is highly effective in preventing transmission among health care workers, and from the workers to patients. The Secretary, at minimum, reasonably so found, and he took action on that basis to fulfill his responsibility to protect the health and safety of program beneficiaries while they receive care that these programs pay for. The APA requires nothing more than that. *See Prometheus Radio Project*, 141 S. Ct. at 1158.

Reliance on Adequate Data. After reviewing a 73-page rule, with voluminous sources cited throughout 261 footnotes in the document, Plaintiffs purport to have located two instances in which the Secretary relied on incomplete data in making his finding that his rule was needed to protect the health of patients at federally-funded facilities. The Secretary's evaluation of the scientific evidence that was available to him is owed great deference. *See Prometheus Radio Project*, 141 S. Ct. at 1160.

Plaintiffs first contend that the Secretary erred in relying on reports from 2020 when he noted

that patients have been forgoing medical care to avoid the risk of contracting the virus from health care workers. Br. 25. But he explicitly acknowledged—on the basis of reports from this year—that, "[w]hile avoidance of necessary care appears to have abated somewhat since the first months of the COVID-19 pandemic, it remains an area of concern for many individuals." 86 Fed. Reg. at 61,558, AR00004. In contrast, Plaintiffs provide only unadorned assertions that patients no longer have any concerns over the risk of contracting the virus in health care settings. The Secretary's concern related to patients "refusing care from unvaccinated staff," *id.*.; regardless of the availability of vaccines, unvaccinated staff raise the same fears as before, which is precisely why "it remains an area of concern." *Id.*

Second, Plaintiffs dispute a single data point cited in the rule, which recited that 64% of staff at long-term care facilities had been vaccinated as of August 28, 2021. Br. 25. They do not claim that this figure is incorrect. Rather, they assert that the Secretary erred in finding this to be a "suboptimal" vaccination rate, because an early study cited in the rule found benefits for vaccination rates of 60% and above. *Id.* at 25-26. But the Secretary did not rely solely on the referenced study to conclude that a 64% rate was suboptimal. Rather, he relied upon a wide range of data, including a study showing that health care units with COVID-19 cases "had lower staff vaccination rates," and a study showing that transmission of COVID-19 to patients "was linked to unvaccinated persons." 86 Fed. Reg. at 61,558, AR00004. In addition, he discussed a study of "breakthrough infections among healthcare workers," in which "virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections." *Id.* Thus, "fewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients[.]" *Id.* The Secretary reasonably found that greater vaccination rates provide greater protection for patients.

Moreover, national data on average vaccination rates are subject to "sizable regional differences," which range from "lows of 56 percent to highs of over 90 percent, depending upon [the] State." *Id.* at 61,559, AR00005. Although Plaintiffs note that the average vaccination rate in long-term care facilities has increased since the rule was written, Br. 26, unfortunately, those regional differences have remained. For instance, while several states have now achieved vaccination rates well over 90

percent for staff in nursing homes, a full 15 states, including Texas, have vaccination rates below 70 percent for such staff. CDC, *COVID-19 Vaccination Coverage and Reporting among Staff in Nursing Homes, by State and Week – United States* (Nov. 23, 2021) (linked to in *Nursing Home COVID-19 Vaccination Data Dashboard,* (choose *COVID-19 Vaccination Coverage and Reporting among Staff in Nursing Homes, by State and Week – United States* (Nov. 23, 2021)), https://perma.cc/9AHR-48SK, AR03238).

The Scope of the Rule. Plaintiffs next contend that the rule is overly broad, either because it should have applied only to facilities that care for the elderly and infirm, or because the rule should have exempted personnel without direct contact with patients. Br. 27-28. The Secretary reasonably explained his policy choices on both scores.

Plaintiffs assert that the rule wrongly applies a "blanket mandate" to various types of providers, such as psychiatric residential treatment facilities (PRTFs), which serve younger patients. *Id.* at 27-28. But that misunderstands the Secretary's interest; nowhere in the rule did he claim that his statutory responsibilities extended *only* to the elderly or infirm. Instead, his statutory responsibility—and his asserted interest—is to protect the health and safety of each of the patient populations at health care facilities covered by this rule. *See, e.g.*, 42 U.S.C. § 1396d(h)(1) (incorporating for psychiatric residential treatment facilities, through cross-referenced statutes, the health and safety requirements for hospitals under § 1395x(e)(9)). He further noted that individuals in congregate care settings, such as PRTFs, are at greater risk of acquiring infections, including infection with the virus that causes COVID-19, 86 Fed. Reg. at 61,575, AR00021, and that individuals with underlying medical conditions who are served by covered facilities "are at increased risk for severe illness from COVID-19," *id.* at 61,566, AR00012.

Plaintiffs fault the Secretary for purportedly relying solely on data from nursing homes, but this is incorrect. *See id.* at 61,557, AR00003 (discussing hospital data); 61,558, AR00004 (same). To be sure, the most robust sets of data come from nursing homes, and "similarly comprehensive data" are not available across all provider types. *Id.* The Secretary extrapolated from the data that was available to conclude that "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel [him] to take action." *Id.* The APA permits the Secretary to draw this inference from the available data. "The APA imposes no general obligation on

agencies to conduct or commission their own empirical or statistical studies." *Prometheus Radio Project*, 141 S. Ct. at 1160. Instead, agencies may make "reasonable predictive judgment[s]" based on the data that they do have. *Id.*; *see also Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 453-55 (5th Cir. 2021).

Plaintiffs also contend that the rule is overbroad because it requires the vaccination of all staff that may come into contact with others at the site of care. Br. 28. But the Secretary explained at length why these personnel should be covered by the vaccination requirements. *See, e.g.,* 86 Fed. Reg. at 61,570-71, AR00016-17. He concluded that these persons may "encounter fellow employees, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities[.]" *Id.* at 61,568, AR00014. Given the high transmissibility of the virus and demonstrated rates of transmission of the virus among health care workers, this conclusion was eminently reasonable. *See id.* at 61,557, AR00003. The Secretary elected to exempt persons who perform only infrequent tasks at health care facilities, and directed providers to consider "frequency of presence, services provided, and proximity to patients and staff" in evaluating which of their employees would be covered under the rule. *Id.* at 61,571, AR00017. He considered a broader exemption to "exclud[e] individual staff members who are present at the site of care less frequently than once per week from these vaccination requirements, but [was] concerned that this might lead to confusion or fragmented care." *Id.* at 61570-71, AR00016-17. Accordingly, the rule provides strong protection to patients by requiring the vaccinations of health care personnel who interact with Medicare and Medicaid patients directly, along with staff who pose a danger of indirect transmission of the virus.[9]

Ultimately, Plaintiffs' argument boils down to a dispute over where to draw the line with a vaccination requirement. But an agency "is not required to identify the optimal threshold with pinpoint precision. It is only required to identify the standard and explain its relationship to the underlying

[9] At the same time, the rule exempts from the vaccine requirements those staff who "telework full-time," and vendors and other professionals who perform infrequent, non-healthcare services. 86 Fed. Reg. at 61,571, AR00017. The Secretary also found that it would be "overly burdensome" to mandate that all providers and suppliers ensure COVID-19 vaccination "for all individuals who enter the facility." *Id.*

regulatory concerns." *WorldCom, Inc. v. FCC*, 238 F.3d 449, 461-62 (D.C. Cir. 2001); *see also ExxonMobil Gas Mktg. Co. v. Fed. Energy Regul. Comm'n,* 297 F.3d 1071, 1085 (D.C. Cir. 2002) ("We are generally unwilling to review line-drawing performed by the Commission unless a petitioner can demonstrate that lines drawn are patently unreasonable, having no relationship to the underlying regulatory problem.") (internal quotation and alterations omitted). Although Plaintiffs would prefer for the rule to cover fewer health care staff, or fewer types of providers, the APA does not permit them to "substitute [their] policy judgment for that of the agency." *Prometheus Radio Project*, 141 S. Ct. at 1158. It was plainly reasonable for the Secretary to pursue robust protection for patients by requiring vaccination of the categories of staff set forth above, and reasonableness is all the APA requires. *See id.*

Staff Shortages in Health Care Facilities. The Secretary also reasonably concluded that high rates of SARS-CoV-2 transmission among health care staff have contributed to a shortage of health care workers, and that his vaccination rule would alleviate this problem. Many health care workers have missed work due to SARS-CoV-2 infection, and these absences have disrupted patient access to care. 86 Fed. Reg. at 61,559, AR00005. There have been at least 500,000 reported COVID-19 cases, and at least 1,900 reported COVID-19 deaths, among health care staff; the true figures are likely much higher. *Id.* And the rate of infection among health care staff has increased dramatically with the Delta variant's rise. *Id.* These trends are driven by health care staff vaccination rates that remain too low to protect staff and patients from the virus. *Id.* The Secretary thus fully explained that his rule would help to alleviate staffing shortages at health care facilities, "particularly during periods of community surges in SARS–CoV–2 infection, when demand for health care services is most acute," because "COVID-19 case rates among staff have also grown in tandem with broader national incidence trends since the Delta variant's emergence." *Id.* at 61,569-70, 61,585, AR00015-16, AR00031.

Plaintiffs protest that they predict that a substantial portion of health care workers will choose to leave their jobs rather than be vaccinated, thereby threatening the operation of health care facilities. Br. 17, 20-21, 30. The Secretary considered this possibility and rejected it, after reviewing the empirical evidence that has developed in recent months with regard to the effect of government-imposed or

privately-imposed vaccination requirements.

The Secretary noted numerous health care employers throughout the country have implemented COVID-vaccine requirements. 86 Fed Reg. at 61,566, AR00012. These policies have been overwhelmingly successful, even among health care workers who were previously hesitant to obtain vaccination. *Id.* For example, after Houston Methodist implemented a vaccination requirement for practitioners at its facilities, it achieved a 99% compliance rate with that requirement among its employees and physicians. *Id.* at 61,566 n.131, AR00012 n.131 (citing Todd Ackerman, *Houston Methodist Requires COVID-19 Vaccine for Credentialed Doctors* (June 8, 2021), https://perma.cc/CL72-V3UE, AR01645). Novant Health, similarly, achieved 98.6% compliance with its mandatory vaccination requirement for its staff. *Id.* at 61,566 n.132, AR00012 n.132 (citing *Novant Health Update on Mandatory COVID-19 Vaccination Program for Employees* (Sept. 21, 2021), https://perma.cc/67QT-PD4R, AR03234).

The State of New York also reported a 92% compliance rate with its vaccine requirement, for all 650,000 hospital and nursing home workers in that state. 86 Fed. Reg. at 61,569 n.159, AR00015 n.159 (citing New York Times, *Thousands of N.Y. Healthcare Workers Get Vaccinated Ahead of Deadline* (Sept. 28, 2021), AR 04173)). Additional operators of more than 250 long-term care facilities around the country have achieved greater than 95%, and in some cases 100%, vaccination rates after imposing their own requirements. *Id.* at 61,569 n.158, AR00015 n.158 (citing Ezekiel J. Emanuel and David J. Skorton, *Mandating COVID-19 Vaccination for Health Care Workers*, Annals of Internal Medicine (Sept. 2021), https://perma.cc/WJ9H-8KZC, AR02183).

On the basis of this evidence, a coalition of more than fifty professional health care associations, including the American Medical Association, the American Nurses Association, and the National Association for Home Care and Hospice, concluded that vaccination requirements are in the best interest of their memberships, of patients, and of health care facilities. 86 Fed. Reg. at 61,565, AR00011. These organizations represent millions of workers throughout the U.S. health care industry, including groups representing doctors, nurses, long-term care workers, home care workers, pharmacists, physician assistants, public health workers, hospice workers, and epidemiologists. *Id.* at

61,565 & n.122, AR00011 n.122 AR02127.

The Secretary recognized that there was some uncertainty as to how many employees would leave their jobs as a result of a vaccination rule, but concluded that it was more likely that any such effect would be more than offset by reduced staff absenteeism from a reduction in illnesses, as well as a return to work of employees who have stayed out of the workforce for fear of contracting SARS-CoV-2. *Id.* at 61,608, AR00054. These effects would be dwarfed, moreover, by the ordinary degree of churn in the market of labor in the health care industry. In any given year, it is typical for about 2.66 million employees in health care settings to be new hires, in comparison to a total workforce of 10.4 million employees. *Id.* Health care providers are accustomed to regularly finding and replacing employees, and there is no reason to believe that the need to find staffing will be noticeably more onerous as a result of the vaccination rule, even if some unvaccinated health care workers leave for other employment and some vaccinated workers seek jobs in health care facilities. *Id.* at 61,608-09, AR00054-55.

Plaintiffs attempt to dispute these points by offering declarations outside the administrative record, which should be disregarded. In any event, none of their evidence casts doubt on the Secretary's findings. First, they offer six declarations from employees of Houston Methodist, each of whom state that they have resigned, or will resign, from their employment there as a result of that health system's vaccination requirement. App'x to Br. at Exs. D, E, G, I, J, & L. But, as noted above, Houston Methodist achieved a 99.5% vaccination rate with its requirement. 86 Fed. Reg. 61,569, AR00015. The fact that fewer than 1% of that health system's employees refused to comply does not in any way undermine the Secretary's findings. Plaintiffs also refer to a single hospital in rural Texas that currently has only 56% of its staff vaccinated, due to "personal, medical, and religious concerns." Br. 30. But they fail to account for the fact that the rule permits employees to seek exemption on such bases from their employers. 86 Fed. Reg. at 61,572, AR00018. In addition, Plaintiffs pointedly do not make any assertion that the remaining unvaccinated employees will refuse a vaccine following implementation of the rule, or provide any basis for such a claim. Plaintiffs thus do not plausibly contend that even this single hospital may encounter difficulties in compliance, let alone that the

Secretary was arbitrary in his findings.

In sum, after reviewing the real-world evidence of the success of vaccination requirements to date, the Secretary predicted that his rule would "result in nearly all health care workers being vaccinated." *Id.* at 61,569, AR00015. The Fifth Circuit has emphasized that, in an APA challenge, an agency's predictive judgments should be accorded deference. *See, e.g., Huawei Techs.*, 2 F.4th at 455 ("[W]e are limited to considering whether 'the [agency] made a reasonable predictive judgment based on the evidence it had . . . ."); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 521 (2009); *Newspaper Ass'n of Am. v. Postal Regul. Comm'n*, 734 F.3d 1208, 1216 (D.C. Cir. 2013) ("When, as here, an agency is making 'predictive judgments about the likely economic effects of a rule,' we are particularly loath to second-guess its analysis.") (citation omitted).

Consideration of Alternatives. Plaintiffs next contend that the rule is "inflexible" in that it lacks a consideration of potential alternatives. Br. 31. They assert, first, that the Secretary arbitrarily rejected the option of regular testing. But as Plaintiffs concede, the Secretary explicitly considered this option and rejected it after "review[ing] scientific evidence on testing and [finding] that vaccination is a more effective infection control measure." 86 Fed. Reg. at 61,614, AR00060. Plaintiffs complain that the Secretary did not cite the evidence he relied on in the rule itself, but the APA does not require this. *See* 5 U.S.C. § 553(c) (requiring rules only to recite "a concise general statement of their basis and purpose"). The Secretary's findings are amply supported, for example, by a study showing that testing has been of limited effectiveness in preventing COVID-19 outbreaks, and another finding that certain rapid COVID-19 tests will only detect a fraction of asymptomatic cases**.** *See* Isaac See, et al., *Modeling Effectiveness of Testing Strategies to Prevent COVID-19 in Nursing Homes (COVID-19) in Nursing Homes – United States, 2020*, 73 Clin. Infect. Diseases 792 (Aug. 2, 2021), https://perma.cc/93R6-A3Y4, AR02949; Ian W. Pray, et al., *Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2, Testing at Two University Campuses – Wisconsin, Sept. – Oct. 2020*, 69 Morbidity and Mortality Weekly Report 1642 (Jan. 1, 2021), https://perma.cc/HX2P-MVZG, AR 03307. On the other hand, vaccinations prevent approximately 80% of infections in the first instance, and drastically reduce the risk of significant illness and hospitalization. 86 Fed. Reg. at 61,565, AR00011. The Secretary's

conclusion and explanation that vaccination is more effective in practice than testing in preventing the transmission to others of SARS-CoV-2, in light of this evidence, is plainly sufficient. *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 797–98 (D.C. Cir. 1984).[10]

Second, Plaintiffs err in arguing that the Secretary erred by not exempting those with prior SARS-CoV-2 infections from the scope of his rule. Br. 31. But the Secretary concluded that infection-induced immunity is not equivalent to receiving vaccination for COVID-19, 86 Fed. Reg. at 61,559, AR00005, and that, even among those persons with prior SARS-CoV-2 infections, vaccination provides strong protection against reinfection. *Id.* at 61,585 n.205, AR00031 n.205 AR03415. The Secretary accordingly followed the recommendations of CDC, which has found that the best academic evidence supports the benefits of vaccination for all people, regardless of their infection history. 86 Fed. Reg. at 61,560, AR00006.

In particular, CDC found that among previously infected individuals, "[n]umerous immunologic studies have consistently shown that vaccination of individuals who were previously infected enhances their immune response, and growing epidemiologic evidence indicates that vaccination following infection further reduces the risk of subsequent infection, including in the setting of increased circulation of more infectious variants." *Id.* at 61,560 n.70, AR00006 n.70, AR 02047.

Because the overall weight of the scientific evidence pointed in favor of vaccinations benefiting previously infected individuals, the Secretary reasonably chose not to create an exemption for these persons. 86 Fed. Reg. at 61,614, AR00060. In reviewing agency action, it "is generally not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence." *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 42 (D.D.C. 2018), *aff'd*, 7 F.4th 1201 (D.C. Cir. 2021) (citation omitted).

[10] Plaintiffs argue that the Secretary failed to consider that OSHA, in a separate rulemaking, had allowed for testing as an alternative to vaccination. Br. 31. But the Secretary tailored his rule specifically to the context of Medicare- and Medicaid-funded health care facilities, and found that his vaccination rule was needed to protect vulnerable patients at these locations. That different regulatory tools might be employed by other agencies in different contexts does not undermine this finding.

Third, Plaintiffs contend that the Secretary erred in setting the rule's deadlines for obtaining vaccination or claiming an exemption. They assert that the Secretary failed to consider that some individuals who currently suffer from a SARS-CoV-2 infection may need to delay vaccination. Br. 32. This is meritless; the rule provides an exemption for "those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations." 86 Fed. Reg. at 61,573, AR00019. And, Plaintiffs' contrary claims notwithstanding, Br. 32, the Secretary directly considered whether vaccines were available, and found that supply was sufficient to meet the anticipated demand. 86 Fed. Reg. at 61,610 n.248, AR00056 n.248.

C. The Secretary had good cause to issue the rule on an interim basis.

Notice-and-comment rulemaking is not required "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(C) (incorporating § 553(b)(B) into the Medicare statute). This exception excuses notice and comment where delay could result in serious harm. *See Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004). The Secretary's finding here more than meets that standard.

The Secretary properly found that any delay in issuing the rule "would endanger the health and safety of additional patients and be contrary to the public interest," 86 Fed. Reg. at 61,584, AR00030, given the rule's "life-saving importance." *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981); *see also U.S. Steel Corp. v. U.S. EPA*, 595 F.2d 207, 214 (5th Cir. 1979); *Vista Health Plan, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 18-824, 2020 WL 6380206, at *9 (W.D. Tex. Sept. 21, 2020). The Secretary projected that the "total lives saved under this rule may well reach several hundred . . . or perhaps several thousand a month." 86 Fed. Reg. at 61,612, AR00058. Any further delay in issuing the rule "would do real harm," *U.S. Steel Corp.*, 595 F.2d at 214, in the form of lives lost that would have been saved under the rule. *See also Sorenson Comm'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) (although good cause is rarely invoked, "we have approved an agency's decision to bypass notice and comment where delay would imminently threaten life").

Rather than grapple with this reality, Plaintiffs argue that the Secretary could have started his

rulemaking earlier, given that "the vaccines have been available for nearly a year." Br. 18-19. But he explained that he initially chose a policy of "encourag[ing] rather than mandat[ing] vaccination," believing that a combination of other efforts would be "adequate," 86 Fed. Reg. at 61,583, AR00029, and only issued the vaccination rule after first determining that these other efforts were insufficient. *See id.* at 61,559, 61,583, AR00005, AR00029. Given data showing that SARS-CoV-2 is highly transmissible between health-care workers and patients in hospitals, and the growth in case rates among health care workers, *id.* at 61,585, AR00031, he found that delaying the rule "would contribute to additional negative health outcomes for patients including loss of life," *id.* at 61,584, AR00030.

Although Plaintiffs fault the Secretary for not immediately issuing a rule when the President announced a plan to do so in September, the fact that the Secretary completed a 73-page rule, with an analysis of over 200 cited sources, in less than 2 months shows that he acted with appropriate dispatch in the face of the crisis.[11] *Compare Asbestos Info. Ass'n/N. Am. v. OSHA*, 727 F.2d 415, 423 (5th Cir. 1984) (recognizing that good cause may be met even when the agency acts years after learning of a serious health risk, so long as the agency "offer[s] some explanation of its timing in promulgating" the rule, and it "acted in response to new awareness of the danger") *with* 86 Fed. Reg. at 61,583-86, AR00029-32.

The Secretary reasonably predicted that a renewed surge, the coming flu season, or a combination of the two will further exacerbate the strain on the health care system. Deference is owed to his predictive judgment on this score. *See Huawei Techs.*, 2 F.4th at 455. First, he identified "emerging indications of potential increases" in cases, indications which are consistent with evidence that "[r]espiratory virus infections typically circulate more frequently during the winter months." 86 Fed. Reg. at 61,584, AR00030. Second, he explained that the coming flu season "presents an additional threat to patient health and safety," given that the interaction of the flu virus with the COVID-19 virus could lead to particularly severe outcomes for health care facility patients. *Id.* While he acknowledged that the "intensity" of the coming flu season "cannot be predicted," he identified

[11] *See* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 N.W. L. Rev. 471, 513-19 (2011) (on average, federal rulemakings take 1.3 years to complete).

"[s]everal factors" that "could make this flu season more severe." *Id.* Finally, he cited "[p]reliminary evidence suggest[ing] that a combination of infections with influenza and SARS-CoV-2 would result in more severe health outcomes for patients than either infection alone." *Id.*

Based on all of these factors, the Secretary found that the strain on the health care system produced by the coincidence of persistently high (or rising) COVID-19 cases together with an imminent and potentially severe flu season would "adversely impact patient access to care and care quality" and, therefore, "it is imperative that the risk for healthcare-associated COVID-19 transmission be minimized during the influenza season." *Id.* Because flu incidence is highest "between December through March" and "COVID-19 vaccines require time after administration for the body to build an immune response," he reasonably determined that "a staff COVID-19 vaccination requirement for the providers and suppliers identified in this rule cannot be further delayed." *Id.* In this regard, the Secretary outlined the considered, supported reasons that his rule is necessary *right now* to protect patients at Medicare- and Medicaid-funded health care facilities. *Id.* Although Plaintiffs dispute the Secretary's good-cause findings by citing to the Fifth Circuit's grant of a stay application in *BST Holdings,* 2021 WL 5279381, that case involved a rule issued by a different agency on a different record, and does not speak to the Secretary's findings in the specific context of the need to protect vulnerable patients in facilities like hospitals and nursing homes.

Plaintiffs also fault the Secretary for issuing his rule at a time when "the situation has only improved" with "more individuals continue to be vaccinated, and COVID-19 infections . . . trending downward." Br. 19. (This is no longer the case, as explained *supra* n.1.) Although Plaintiffs assert that "CMS offers nothing to explain why now," *id.*, in fact the Secretary identified "emerging indications of potential increases," and foresaw that a renewed surge during the winter flu season would exacerbate the strain on the health care system, as explained above. 86 Fed. Reg. at 61,584, AR00030.

Because the Secretary had good cause to dispense with notice-and-comment rulemaking, Plaintiffs' two additional procedural arguments are unavailing. First, they contend that the Secretary violated 42 U.S.C. § 1395z. Br. 22. That statute directs that, "[i]n carrying out his functions, relating to determination of [some, but not all, of the] conditions of participation by providers of services . . .

[at issue here], the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies[.]" 42 U.S.C. § 1395z. The Secretary found that "[a]ny delay in the implementation of this rule would result in additional deaths and serious illnesses among health care staff and consumers, further exacerbating the newly-arising, and ongoing, strain on the capacity of health care facilities to serve the public." 86 Fed. Reg. at 61,567, AR00013. Based on that finding of the existence of an emergency, he determined that there are no entities with which it would be "appropriate to engage in these consultations in advance of issuing" the interim rule, but noted that he would engage in consultations following the rule's issuance "in carrying out [his] functions." *Id.*

This determination is entitled to deference from this Court, for the same reasons that the Secretary's decision to issue an interim final rule is so entitled. *See The GEO Grp., Inc. v. Newsom*, 15 F.4th 919, 930 (9th Cir. 2021) (statutory language authorizing agency to take "appropriate" action "is a hallmark of vast discretion"). *See also Kisor v. Wilkie*, 139 S. Ct. 2400, 2448 (2019) (Kavanaugh, J., concurring in the judgment) ("broad and open-ended terms" like "'appropriate'" "afford agencies broad policy discretion"); *Alon Refin. Krotz Springs, Inc. v. U.S. EPA*, 936 F.3d 628, 655 (D.C. Cir. 2019), *cert. denied sub nom.*, *Valero Energy Corp. v. EPA*, 140 S. Ct. 2792 (2020) ("nor does the phrase 'as appropriate' itself specify a particular temporal dimension").

Second, Plaintiffs contend that the Secretary's issuance of his rule on an emergency basis violated 42 U.S.C. § 1302(b), which requires the preparation of a regulatory impact analysis upon the publication of a "notice of proposed rulemaking," *id.* § 1302(b)(1), or upon the publication of a "final version of a rule or regulation with respect to which an initial regulatory impact analysis is required by paragraph (1)," *id.* § 1302(b)(2). This requirement does not apply here. The Secretary did not publish a notice of proposed rulemaking, and this is not the final version of a rule with respect to which an initial regulatory impact analysis was required. The Secretary accordingly reasonably found that the statute did not require an analysis under either paragraph; the plain text of the statute "only applies to final rules for which a proposed rule was published," 86 Fed. Reg. at 61,613, AR00059, not to interim final rules, such as this one, that the Secretary publishes to address emergencies such as an imminent threat to patients' lives. *See Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519,

524 (1978) (courts are not free to impose additional procedural requirements on rulemakings beyond those expressed in statute); *Abubaker Abushagif v. Garland*, 15 F.4th 323, 332 (5th Cir. 2021).

III. THE REMAINING INJUNCTION FACTORS REQUIRE DENIAL OF PLAINTIFFS' MOTION.

A. Plaintiffs fail to establish irreparable harm.

Plaintiffs also cannot demonstrate likely irreparable harm. This showing "is required for injunctive relief." *Motient Corp. v. Dondero*, 529 F.3d 532, 538 (5th Cir. 2008).

1. Plaintiffs suffer no cognizable harm to their "sovereign interests" at all, let alone a harm of the type required for equitable relief. Br. 33. Absent an allegation that the State's own enforcement efforts have been hampered, Plaintiffs do not have a cognizable interest for Article III purposes in the abstract question whether state law is preempted. *See Va. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 270 (4th Cir. 2011). And, as for Plaintiffs' quasi-sovereign interests or *parens patriae* interests, Br. 34, Plaintiffs have no standing to sue the federal government in that capacity, and therefore cannot assert that they have been irreparably harmed on the basis of such interests, *see Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982) ("A State does not have standing as *parens patriae* to bring an action against the Federal Government"); *cf. Texas v. Biden*, ---F. Supp. 3d---, No. 2:21-cv-067-Z, 2021 WL 3603341, at *12 (N.D. Tex. Aug. 13, 2021) (Kacsmaryk, J.) (contrasting a permissible suit in which a State asserts its own rights under federal law with one in which a State is impermissibly "attempting to protect its citizens from the operation of [the federal law]"), *appeal filed*, No. 21-10806 (5th Cir. Aug. 16, 2021).

2. Plaintiffs' claims of irreparable harm are also speculative. They rely on conjecture that health care services "*may*" be disrupted if unvaccinated workers are terminated. Br. 35 (emphasis added). But "[t]here must be a *likelihood* that irreparable harm will occur. . . . a preliminary injunction will not be issued simply to prevent the possibility of some remote future injury." *United States v. Emerson*, 270 F.3d 203, 262 (5th Cir. 2001). As discussed above, the Secretary acted against a backdrop in which many health care workers "already comply with employer or State government vaccination requirements." 86 Fed. Reg. at 61,567, AR00013. He acknowledged concerns that some workers are

reluctant to obtain vaccinations, but he found—based on real-world experience with COVID-19 vaccination requirements in a variety of settings—that the vaccination rule was likely to be highly successful, and that the vast majority of non-exempt individuals would obtain vaccination, even in cases where individuals earlier had expressed an initial unwillingness to do so. *Id.* at 61,569, AR00015; *see also* Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy & Efficiency Analysis, 86 Fed. Reg. 63,418, 63,422 (Nov. 16, 2021) (Office of Management and Budget analysis noting that "Tyson Foods reported more than 96 percent of its workforce is now vaccinated" after imposing a vaccination requirement). Moreover, given the high degree of churn in the health care workforce—about one quarter of a health care facility's workers are new hires in any given year, on average—the Secretary reasonably found that any effect of unvaccinated workers leaving jobs with health care facilities, or of vaccinated workers newly seeking employment there, would be dwarfed by this regular feature of the health care industry. 86 Fed. Reg. at 61,608, AR00054.

Plaintiffs identify no evidence that health care workers will actually leave their jobs in large numbers if the vaccination rule remains in effect. They cite declarations that suggest that the rule will "increase the likelihood" of a staffing shortage, Appx. to Br., Exs. F, H, but they have not identified any facilities that actually were subject to vaccination requirements and that lost significant numbers of employees. In a virtually identical suit, and on the basis of declarations substantively the same as those Plaintiffs cite here, another district court concluded that the plaintiffs had failed to establish that the harm they fear will *in fact* occur, as required to obtain emergency injunctive relief. *See Florida v. Dep't of Health & Human Servs.*, --- F. Supp. .3d ---, 21-cv-2722, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021) (denying temporary restraining order for, *inter alia*, lack of irreparable harm); *cf. Florida v. Dep't of Health & Human Servs.*, 21-cv-2722, slip op. *1 (N.D. Fla. Nov. 27, 2021) (denying plaintiff's emergency motion for injunction pending appeal).

Moreover, Plaintiffs fail to set forth any evidence that the labor loss they fear would outstrip the staffing losses and absences resulting from COVID-19 exposures, let alone the normal churn in a health care labor market where about one quarter of an average health care facility's employees are

new hires in any given year. The Secretary considered this issue, and found that "some hospitals and health care systems are currently experiencing tremendous strain due to high case volume, coupled with persistent staffing shortages due, at least in part, to COVID-19 infection or quarantine following exposure." 86 Fed. Reg. at 61,583, AR00029. Nor do Plaintiffs provide any evidence that in the absence of the vaccination rule, they will be able to stave off additional staffing problems.

And critically, even if certain hospital providers were not able to immediately comply with the rule, the result would not be immediate termination from Medicare and Medicaid. As CMS has explained in guidance on the rule, its "goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance." CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (External FAQ) at 10 (last visited Nov. 24, 2021), https://perma.cc/7W7B-CNPR. Thus, Plaintiffs cannot show that any injury will immediately or certainly occur.

3. Plaintiffs' further assertion that they suffer irreparable harm because the state survey agency is "commandeered" into enforcing the rule, Br. 35, mischaracterizes the role of state survey agencies. The statute permits States to enter agreements with the Secretary to survey facilities' compliance with the conditions of participation in Medicare and Medicaid. These agreements are entirely voluntary. *See* 42 U.S.C. § 1395cc(a). Moreover, survey agencies do not enforce the conditions of participation; they instead report their findings to CMS, which determines whether to pursue a sanction. 42 C.F.R. §§ 488.10(a), 488.26(c)(1). This case is entirely unlike the "coercion" at issue in *NFIB*, which held that Congress could not make the entirety of a State's traditional Medicaid funding contingent on participation in a new program to provide health coverage for all low-income adults. Here, the Secretary is not "enlisting the States in a new health care program," *Nat'l Fed'n of Indep. Business v. Sebelius*, 567 U.S. 519, 584 (2012). *See Gruver v. La. Bd. of Supervisors for La. State Univ. Agric. & Mech. Coll.*, 959 F.3d 178, 184 (5th Cir.), *cert. denied*, 141 S. Ct. 901 (2020). He is simply applying the existing provisions of the Medicare and Medicaid statutes to fulfill his statutory duty to protect the health and safety of beneficiaries of these programs. And the magnitude of federal funding at issue for surveys is miniscule compared to the funds that were at stake in *NFIB*.

Accordingly, because Plaintiffs cannot show that any harm they fear is in fact likely, they are not entitled to injunctive relief. *See Motient Corp.*, 529 F.3d at 538.

B. Plaintiffs fail to establish that the balance of equities and public interest factors favor the requested injunction.

The third and fourth requirements for issuance of a preliminary injunction—the balance of harms and whether the requested injunction will disserve the public interest—"merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, these considerations tilt decisively in Defendants' favor.

An injunction against the rule would harm the public interest in slowing the spread of COVID-19 among millions of health care workers and patients at federally-funded health care facilities. The Secretary projects that the vaccination rule may save hundreds, and potentially thousands, of lives each month. 86 Fed. Reg. at 61,612, AR00058. In the context of this pandemic, "federal courts across the country have routinely concluded that undoing orders deemed necessary by public health officials and experts to contain a contagious and fast-spreading disease would result in comparatively more severe injury to the community." *Chambless Enterprises, LLC v. Redfield*, 508 F. Supp. 3d 101, 123 (W.D. La. 2020) (citation omitted). In evaluating the balance of harms, "courts properly decline to second-guess the judgments of public health officials." *Id.* (internal citations omitted).

By comparison, any theoretical harm "pales in comparison to the significant loss of lives that Defendants have demonstrated could occur" if the rule is enjoined. *Id.* (citation omitted). As explained above, Part III.A, Plaintiffs' claimed harms are speculative. Nowhere do they dispute the life-saving effects of vaccination; in fact, in discussing the public interest prong, they fail even to acknowledge the unparalleled American casualties from COVID-19. Although they argue that the rule will cause health care staff to leave their jobs in large numbers, they have set forth no evidence to show that the vaccination rule will actually have that effect. In fact, as noted in the rule, there are clear examples of requirements having exactly the effect that the Secretary intends—increasing the percentage of vaccinated staff to very high levels. 86 Fed. Reg. at 61,569, AR00015.

Moreover, "[t]here is inherent harm to an agency in preventing it from enforcing regulations

that Congress found it in the public interest to direct that agency to develop." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008), *aff'd*, 330 F. App'x 919 (Fed. Cir. 2009). Congress has charged the Secretary with the responsibility to protect the health and safety of individuals receiving care and services from Medicare and Medicaid providers. *See, e.g.*, 42 U.S.C. §§ 1395x(e)(9); 1395i–3(d)(4)(B). The public interest favors allowing the Secretary to fulfill these responsibilities.

IV. ANY INJUNCTIVE RELIEF SHOULD BE APPROPRIATELY LIMITED.

If the Court disagrees with Defendants' arguments, any relief should be no broader than necessary to remedy the demonstrated irreparable harms of the specific Plaintiffs in this case. "A plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). Any relief should be limited in two respects.

First, any injunction should apply only to those aspects of the rule for which the Court finds Plaintiffs have met their burden under the four-factor test for emergency relief. The Supreme Court has held a regulation severable where severance would "not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (invalidating only the provision of a regulation that exceeded the agency's statutory authority). Severability clauses, such as the one in the rule, *see* 86 Fed. Reg. at 61,560, AR00006, create a presumption that the validity of the entire regulation is not dependent on the validity of any specific unlawful provision if that unlawful provision would not impair the function of the regulation as a whole. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987).

Second, any injunctive relief should be limited, at most, to facilities operated by Plaintiffs. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill*, 138 S. Ct. at 1933; *see also id.* at 1934 (citing *Daimler Chrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)); *Madsen*, 512 U.S. at 765. Indeed, Plaintiffs have no interest in whether facilities in other States are subject to the rule during the pendency of this lawsuit (and in fact, if their allegations

concerning trends among health care workers are to be believed, they would benefit from relief being circumscribed within their own borders to facilities they themselves operate), nor standing to assert claims on behalf of facilities in Texas that Plaintiffs do not operate. Plaintiffs' claims would be fully redressed through a preliminary injunction prohibiting the Secretary from "implementing" or "enforcing" the rule against only those facilities that Plaintiffs themselves operate.

Nationwide relief would be particularly harmful here given that Texas filed this suit alone, and other district courts are currently considering similar challenges brought by other States. A nationwide injunction would render the district court's order in *Florida*, as well as any additional orders that might follow from other courts considering similar claims, meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiffs' claims against the rule's operation in other jurisdictions. Moreover, many States are not challenging the vaccination rule. There is no reason why Plaintiffs' disagreement with the rule should govern the rest of the country. *See California v. Azar*, 911 F.3d 558, 583 (9th Cir. 2018) ("The detrimental consequences of a nationwide injunction are not limited to their effects on judicial decisionmaking. There are also the equities of non-parties who are deprived the right to litigate in other forums."); *see also id.* at 582-84 (vacating nationwide scope of injunction in facial challenge under the APA).[12]

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion should be denied.

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Respectfully submitted,

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[12] At all events, the application for a temporary restraining order should be denied. Because the preliminary injunction motion is fully briefed, "no purpose would be served or furthered by the issuance of a temporary restraining order." *Corp. Relocation, Inc. v. Martin*, No. 3:06-CV-232-L, 2006 WL 4101944, at *2 (N.D. Tex. Sept. 12, 2006).

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